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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/703,798	11/02/2000	Amanda Johanne Kiliaan	BO 44102 ACW	2164

466 7590 11/17/2004

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EXAMINER	
DAVIS, RUTH A	

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 11/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/703,798	KILIAAN ET AL.	
	Examiner	Art Unit	
	Ruth A. Davis	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 October 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *56-75* is/are pending in the application.

4a) Of the above claim(s) *73-75* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *56-72* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant's amendment, response and declaration filed October 18, 2004 has been received and entered into the case. Claims 39 – 55 are canceled; claims 56 – 75 are added. The submitted declaration and all arguments have been fully considered.

Newly submitted claims 73 – 75 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Claims 73 – 75 are drawn to a method of treating/preventing vascular disorders, which is an independent and distinct invention from the claims drawn to a composition (which have been previously considered).

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 73 – 75 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 56 – 72 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a composition which treats dementia syndromes,

cognitive degeneration or hearing loss, does not reasonably provide enablement for a composition that prevents the aforementioned conditions. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Claim 56 and its dependents recite "for the prevention" of dementia syndromes, cognitive degeneration or hearing loss. "Prevention" provides the expectation that the disorder/condition does not occur in response to a challenge or initiating event. While there is no requirement that prevention must be absolute in all cases, there is a reasonable expectation that some element of prevention can be shown. The standard for such is extremely high, and it is expected that the showing will be actual rather than implied, prophetic, or with a model. The standard of enablement is higher for such inventions because effective preventions of disease conditions are relatively rare and may even be unbelievable in the absence of strong supporting evidence. While the specification does teach composition that may treat dementia symdromes, cognitive degeneration, or hearing loss, the specification is absent working examples of how the composition would prevent the same. Moreover, this is not a showing that the disorders can be prevented as claimed.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 66 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 66 is drawn to a composition however is rendered vague and indefinite because it is unclear if fraction (c) rather comprises copper and zinc; or further comprises copper and zinc.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 56, 59 – 62, 65, 69 – 70 and 72 are rejected under 35 U.S.C. 103(a) as being unpatentable over Horrobin, Della Valle and Fugh-Berman.

Applicant claims a composition for treating and/or preventing dementia syndromes, cognitive degeneration or hearing loss, the composition comprising (a) one omega 3 fattty acid selected from EPA and DHA; (b) at least two different phospholipids selected from phosphatidylserine, phosphatidylinositol, phosphatidylcholine and phosphatidylethanolamine; and (c) at least one of folic acid, vitamin B12, B6, magnesium or zinc. Fraction (a) further comprises at least one of linoleic acid, alpha-linloenic acid, and optionally an omega 6 fatty acids selected from DHGLA and AA; wherein the ratio or EPA+DHA+DHGLA+AA to the total amount of linoleic and alpha-linoleic acid is above 0.4 :1. The composition further comprises (d) citrates or citric acid; or (h) ginkgo biloba extract. Fraction (c) further comprises one of SAMe, choline, betaine or copper; the composition is a nutritional supplement. Specifically, the composition comprises at least 0.2 g phospholipids; 0.1 g phosphatidylserine; or at least 120 mg long chain fatty acids, 200 mg phospholipids, 200 micrograms folic acid, and 500 mg citrate.

Horrobin teaches compositions comprising essential fatty acids for treating dementia and Alzheimer's disease (abstract). Specifically, linoleic acid, alpha linoleic acid, DGLA, EPA, DHA, AA are combined in specific ratios and amounts (col.2 line 36-59). The composition further comprises citrates (claims, examples).

Della Valle teaches compositions comprising phosphatidylserine and phosphatidylethanolamine in specific ratios for treating dementia (abstract, col.5 line 44-59). Specifically, the compositions comprise 60 – 75% phosphatidylserine and 25 – 40% phosphatidylethanolamine (abstract).

Fugh-Berman teaches ginkgo biloba (p.715), vitamin B12, folate (p.721) and SAMe (p.722) for treating dementia, memory problems and cognitive function.

The above references do not teach all of the ingredients together in the same composition. However, at the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to combine the instant ingredients for their known benefit, as disclosed by the cited references above, since each is well known in the art for their claimed purpose. Although the references do not specifically teach the exact amounts and/or ratios, it would have been well within the purview of one of ordinary skill in the art to optimize such parameters as a matter of routine experimentation. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by the cited references to combine the instant ingredients with a reasonable expectation for successfully obtaining a composition for treating and/or preventing dementia syndromes and cognitive degeneration. This rejection is based on the well established proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients, *In re Sussman,* 1943 C.D. 518.

Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of evidence to the contrary.

8. Claims 56 – 58 arerejected under 35 U.S.C. 103(a) as being unpatentable over Horrobin, della Valle, Fugh-Berman and Taiyo Fishery Co.

Applicant claims a composition for treating and/or preventing dementia syndromes, cognitive degeneration or hearing loss, the composition comprising (a) one omega 3 fattty acid selected from EPA and DHA; (b) at least two different phospholipids selected from phosphatidylserine, phosphatidylinositol, phosphatidylcholine and phosphatidylethanolamine;

and (c) at least one of folic acid, vitamin B12, B6, magnesium or zinc. Fraction (b) comprising PC, PE and PS; and the weight ration of PC and PE to PS is from 0.5 – 20:1

Horrobin teaches compositions comprising essential fatty acids for treating dementia and Alzheimer's disease (abstract). Specifically, linoleic acid, alpha linoleic acid, DGLA, EPA, DHA, AA are combined in specific ratios and amounts (col.2 line 36-59). The composition further comprises citrates (claims, examples).

Della Valle teaches compositions comprising phosphatidylserine and phosphatidylethanolamine in specific ratios for treating dementia (abstract, col.5 line 44-59). Specifically, the compositions comprise 60 – 75% phosphatidylserine and 25 – 40% phosphatidylethanolamine (abstract).

Fugh-Berman teaches ginkgo biloba (p.715), vitamin B12, folate (p.721) and SAMe (p.722) for treating dementia, memory problems and cognitive function.

Taiyo Fishery Co teaches compositions of phosphatidylcholine and phosphatidylethanolamine for treating Alzheimer's disease (abstract).

The above references do not teach all of the ingredients together in the same composition. However, at the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to combine the instant ingredients for their known benefit, as disclosed by the cited references above, since each is well known in the art for their claimed purpose. Although the references do not specifically teach the exact amounts and/or ratios, it would have been well within the purview of one of ordinary skill in the art to optimize such parameters as a matter of routine experimentation. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by the cited references to combine the instant ingredients with

a reasonable expectation for successfully obtaining a composition for treating and/or preventing dementia syndromes and cognitive degeneration. This rejection is based on the well established proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients, *In re Sussman,* 1943 C.D. 518.

Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of evidence to the contrary.

9. Claim 63 is rejected under 35 U.S.C. 103(a) as being unpatentable over Horrobin, della Valle, Fugh-Berman and Yu.

Applicant claims a composition for treating and/or preventing dementia syndromes, cognitive degeneration or hearing loss, the composition comprising (a) one omega 3 fattty acid selected from EPA and DHA; (b) at least two different phospholipids selected from phosphatidylserine, phosphatidylinositol, phosphatidylcholine and phosphatidylethanolamine; and (c) at least one of folic acid, vitamin B12, B6, magnesium or zinc. The composition further comprises huperzine A.

Horrobin teaches compositions comprising essential fatty acids for treating dementia and Alzheimer's disease (abstract). Specifically, linoleic acid, alpha linoleic acid, DGLA, EPA, DHA, AA are combined in specific ratios and amounts (col.2 line 36-59). The composition further comprises citrates (claims, examples).

Della Valle teaches compositions comprising phosphatidylserine and phosphatidylethanolamine in specific ratios for treating dementia (abstract, col.5 line 44-59).

Specifically, the compositions comprise 60 – 75% phosphatidylserine and 25 – 40% phosphatidylethanolamine (abstract).

Fugh-Berman teaches ginkgo biloba (p.715), vitamin B12, folate (p.721) and SAMe (p.722) for treating dementia, memory problems and cognitive function.

Yu teaches compounds for treating dementia (abstract) wherein huperzine A is a representative compound (col.4 line 24-25).

The above references do not teach all of the ingredients together in the same composition. However, at the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to combine the instant ingredients for their known benefit, as disclosed by the cited references above, since each is well known in the art for their claimed purpose. Although the references do not specifically teach the exact amounts and/or ratios, it would have been well within the purview of one of ordinary skill in the art to optimize such parameters as a matter of routine experimentation. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by the cited references to combine the instant ingredients with a reasonable expectation for successfully obtaining a composition for treating and/or preventing dementia syndromes and cognitive degeneration. This rejection is based on the well established proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients, *In re Sussman,* 1943 C.D. 518.

Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of evidence to the contrary.

10. Claims 64 – 65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Horrobin, della Valle, Fugh-Berman and Smith.

Applicant claims a composition for treating and/or preventing dementia syndromes, cognitive degeneration or hearing loss, the composition comprising (a) one omega 3 fattty acid selected from EPA and DHA; (b) at least two different phospholipids selected from phosphatidylserine, phosphatidylinositol, phosphatidylcholine and phosphatidylethanolamine; and (c) at least one of folic acid, vitamin B12, B6, magnesium or zinc. Fraction (c) further comprises folic acid and B6; or one of SAME, choline, betaine or copper.

Horrobin teaches compositions comprising essential fatty acids for treating dementia and Alzheimer's disease (abstract). Specifically, linoleic acid, alpha linoleic acid, DGLA, EPA, DHA, AA are combined in specific ratios and amounts (col.2 line 36-59). The composition further comprises citrates (claims, examples).

Della Valle teaches compositions comprising phosphatidylserine and phosphatidylethanolamine in specific ratios for treating dementia (abstract, col.5 line 44-59). Specifically, the compositions comprise 60 – 75% phosphatidylserine and 25 – 40% phosphatidylethanolamine (abstract).

Fugh-Berman teaches ginkgo biloba (p.715), vitamin B12, folate (p.721) and SAMe (p.722) for treating dementia, memory problems and cognitive function.

Smith teaches compositions for treating Alzheimer's disease, comprising folic acid, vitamin B12 (abstract), betaine, and/or vitamin B6 (col.2 line 43-52).

The above references do not teach all of the ingredients together in the same composition. However, at the time of the claimed invention, it would have been obvious to one of ordinary

skill in the art to combine the instant ingredients for their known benefit, as disclosed by the cited references above, since each is well known in the art for their claimed purpose. Although the references do not specifically teach the exact amounts and/or ratios, it would have been well within the purview of one of ordinary skill in the art to optimize such parameters as a matter of routine experimentation. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by the cited references to combine the instant ingredients with a reasonable expectation for successfully obtaining a composition for treating and/or preventing dementia syndromes and cognitive degeneration. This rejection is based on the well established proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients, *In re Sussman,* 1943 C.D. 518.

Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of evidence to the contrary.

11. Claims 65 – 66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Horrobin, della Valle, Fugh-Berman and Hutterer.

Applicant claims a composition for treating and/or preventing dementia syndromes, cognitive degeneration or hearing loss, the composition comprising (a) one omega 3 fattty acid selected from EPA and DHA; (b) at least two different phospholipids selected from phosphatidylserine, phosphatidylinositol, phosphatidylcholine and phosphatidylethanolamine; and (c) at least one of folic acid, vitamin B12, B6, magnesium or zinc. Fraction (c) further comprises one of SAME, choline, betaine, or copper; or zinc and copper at a specified ratio.

Horrobin teaches compositions comprising essential fatty acids for treating dementia and Alzheimer's disease (abstract). Specifically, linoleic acid, alpha linoleic acid, DGLA, EPA, DHA, AA are combined in specific ratios and amounts (col.2 line 36-59). The composition further comprises citrates (claims, examples).

Della Valle teaches compositions comprising phosphatidylserine and phosphatidylethanolamine in specific ratios for treating dementia (abstract, col.5 line 44-59). Specifically, the compositions comprise 60 – 75% phosphatidylserine and 25 – 40% phosphatidylethanolamine (abstract).

Fugh-Berman teaches ginkgo biloba (p.715), vitamin B12, folate (p.721) and SAMe (p.722) for treating dementia, memory problems and cognitive function.

Hutterer teaches compositions comprising choline, zinc and copper (abstract) in specific amounts and ratios (col.4 line 13-23) for treating Alzheimer's disease (abstract).

The above references do not teach all of the ingredients together in the same composition. However, at the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to combine the instant ingredients for their known benefit, as disclosed by the cited references above, since each is well known in the art for their claimed purpose. Although the references do not specifically teach the exact amounts and/or ratios, it would have been well within the purview of one of ordinary skill in the art to optimize such parameters as a matter of routine experimentation. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by the cited references to combine the instant ingredients with a reasonable expectation for successfully obtaining a composition for treating and/or preventing dementia syndromes and cognitive degeneration. This rejection is based on the well established

proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients, *In re Sussman,* 1943 C.D. 518.

Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of evidence to the contrary.

12. Claim 71 is rejected under 35 U.S.C. 103(a) as being unpatentable over Horrobin, della Valle, Fugh-Berman, Smith, Hutterer and Glick.

Applicant claims a composition for treating and/or preventing dementia syndromes, cognitive degeneration or hearing loss, the composition comprising (a) one omega 3 fattty acid selected from EPA and DHA; (b) at least two different phospholipids selected from phosphatidylserine, phosphatidylinositol, phosphatidylcholine and phosphatidylethanolamine; and (c) at least one of folic acid, vitamin B12, B6, magnesium or zinc. Specifically the composition comprises at least 20 mg EPA, 50 mg DHA, 50 mg AA, 200 mg phospholipids, 200 micrograms folic acid, 100 mg magnesium, 5 mg zinc, 2 mg vitamin B6, 2 micrograms vitamin B12 and 1g citrate.

Horrobin teaches compositions comprising essential fatty acids for treating dementia and Alzheimer's disease (abstract). Specifically, linoleic acid, alpha linoleic acid, DGLA, EPA, DHA, AA are combined in specific ratios and amounts (col.2 line 36-59). The composition further comprises citrates (claims, examples).

Della Valle teaches compositions comprising phosphatidylserine and phosphatidylethanolamine in specific ratios for treating dementia (abstract, col.5 line 44-59).

Specifically, the compositions comprise 60 – 75% phosphatidylserine and 25 – 40% phosphatidylethanolamine (abstract).

Fugh-Berman teaches ginkgo biloba (p.715), vitamin B12, folate (p.721) and SAMe (p.722) for treating dementia, memory problems and cognitive function.

Smith teaches compositions for treating Alzheimer's disease, comprising folic acid, vitamin B12 (abstract), betaine, and/or vitamin B6 (col.2 line 43-52).

Hutterer teaches compositions comprising choline, zinc and copper (abstract) in specific amounts and ratios (col.4 line 13-23) for treating Alzheimer's disease (abstract).

Glick teaches administering dietary supplements of magnesium for preventing and controlling dementia and memory loss (abstract, col.3).

The above references do not teach all of the ingredients together in the same composition. However, at the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to combine the instant ingredients for their known benefit, as disclosed by the cited references above, since each is well known in the art for their claimed purpose. Although the references do not specifically teach the exact amounts and/or ratios, it would have been well within the purview of one of ordinary skill in the art to optimize such parameters as a matter of routine experimentation. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by the cited references to combine the instant ingredients with a reasonable expectation for successfully obtaining a composition for treating and/or preventing dementia syndromes and cognitive degeneration. This rejection is based on the well established proposition of patent law that no invention resides in combining old ingredients of known

properties where the results obtained thereby are no more than the additive effect of the ingredients, *In re Sussman,* 1943 C.D. 518.

Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of evidence to the contrary.

13. Claims 67 – 68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Horrobin, della valle, Fugh-Berman and Rabien.

Applicant claims a composition for treating and/or preventing dementia syndromes, cognitive degeneration or hearing loss, the composition comprising (a) one omega 3 fattty acid selected from EPA and DHA; (b) at least two different phospholipids selected from phosphatidylserine, phosphatidylinositol, phosphatidylcholine and phosphatidylethanolamine; and (c) at least one of folic acid, vitamin B12, B6, magnesium or zinc. The composition further comprises (f) one or more selected from carnitine, vitamin B1, B5 and coenzyme Q10; or (g) one or more antioxidants selected from vitamin C, E, lipoic acid, selenium salt and carotenoids.

Horrobin teaches compositions comprising essential fatty acids for treating dementia and Alzheimer's disease (abstract). Specifically, linoleic acid, alpha linoleic acid, DGLA, EPA, DHA, AA are combined in specific ratios and amounts (col.2 line 36-59). The composition further comprises citrates (claims, examples).

Della Valle teaches compositions comprising phosphatidylserine and phosphatidylethanolamine in specific ratios for treating dementia (abstract, col.5 line 44-59). Specifically, the compositions comprise 60 – 75% phosphatidylserine and 25 – 40% phosphatidylethanolamine (abstract).

Fugh-Berman teaches ginkgo biloba (p.715), vitamin B12, folate (p.721) and SAMe (p.722) for treating dementia, memory problems and cognitive function.

Rabien teaches compositions comprising alpha lipoic, panthothenic acid (vitamin B5) and vitamin E for treating Alzheimer's disease (abstract).

The above references do not teach all of the ingredients together in the same composition. However, at the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to combine the instant ingredients for their known benefit, as disclosed by the cited references above, since each is well known in the art for their claimed purpose. Although the references do not specifically teach the exact amounts and/or ratios, it would have been well within the purview of one of ordinary skill in the art to optimize such parameters as a matter of routine experimentation. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by the cited references to combine the instant ingredients with a reasonable expectation for successfully obtaining a composition for treating and/or preventing dementia syndromes and cognitive degeneration. This rejection is based on the well established proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients, *In re Sussman,* 1943 C.D. 518.

Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of evidence to the contrary.

Response to Arguments

Applicant argues that the claimed references do not teach each of the instant ingredients together in a single composition in the amounts and ratios claimed, alone or combined. Applicant additionally argues that the references do not teach the unexpected advantages or benefits of the invention; and provides a declaration exhibiting evidence of the unexpected advantages and results of the claimed composition.

However, these arguments and declaration fail to persuade because as evidenced by the cited references, each of the claimed ingredients were used in the art in compositions for treating dementia syndromes. Although they do not teach the claimed amounts or ratios, it would have been obvious to one of ordinary skill in the art to optimize the amounts of known active ingredients for the same purpose, as a matter of routine practice. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated to combine the instant ingredients and optimize the amounts, with a reasonable expectation for successfully obtaining a composition effective for treating dementia syndromes.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Regarding the declaration, it is noted that the claims are not commensurate in scope with the supplement 2 of the declaration, which exhibits the activities presented and argued. The instant claims do not recite each and every element of the supplement demonstrated to have the

unexpected advantage of improved capillary density, spatial memory qualities and MM performance.

Therefore the references stand rejected for the above reasons.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth A. Davis whose telephone number is 571-272-0915. The examiner can normally be reached on M-H (7:00-4:30); altn. F (7:00-3:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ruth A. Davis
November 13, 2004
AU 1651

LEON B. LANKFORD, JR.
PRIMARY EXAMINER